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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,693

03/13/2006

Peter Jan Zimmermann

26773U

8398

34375 7590 03/18/2009

NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,693	Applicant(s) ZIMMERMANN ET AL.	
	Examiner Laura L. Stockton	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,7 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 8--11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :September 9, 2005 and March 13, 2006.

DETAILED ACTION

Claims 1-11 and 13 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group III (claims 1-3, 5 and 8-11 - drawn to products of formula 1 wherein **X** is NH and **Y** is -CH₂-Ar) in the reply filed on November 24, 2008 is acknowledged. Note, claims 4, 6 and 7 were improperly included in Group III. However, claims 4, 6 and 7 are directed to compounds wherein Y is the group gp.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group III and Claims 4, 6, 7 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no

allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 24, 2008.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on September 9, 2005 and March 13, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5 and 8-11 are rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for a salt of a compound of formula (1), does not reasonably provide enablement for a hydrate or solvate of a compound of formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in making an enablement rejection are summarized as:

- a) the quantity of experimentation necessary,
- b) the amount of direction or guidance presented,
- c) the presence or absence of working examples,
- d) the nature of the invention,
- e) the state of the prior art,
- f) the relative skill of those in the art,

g) the predictability or unpredictability of the art, and

h) the breadth of the claims.

In re Colianni, 195 USPQ 150 (CCPA 1977). In re Rainer, et al., 146 USPQ 218 (CCPA 1965). *Ex parte Formal*, 230 USPQ 546 (BPAI 1986).

a) Determining if a particular compound would form a solvate or hydrate would require synthesis and recrystallization of the compound solvate or hydrate using a variety of solvents, temperatures and humidities. The experimentation for solvates or hydrates is potentially open-ended.

b) The specification merely mentions the Applicant's intention to make solvates and hydrates, without teaching the preparation thereof.

c) While the claims recite solvates and hydrates, no working examples show their formation. As stated in Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190, 1194 (Fed.Cir. 1993):

The specification purports to teach, with over fifty examples, the preparation of the claimed compounds ... However ... there is no evidence that such compounds exist ... [T]he examples ... do not produce the postulated compounds ... [T]here is ... no evidence that such compounds even exist.

The specification shows no evidence of the formation and actual existence of solvates and hydrates. Hence, Applicant must show formation of solvates and hydrates or limit the claims accordingly.

d) The nature of the invention is chemical synthesis of solvates and hydrates, which involves chemical reactions.

e) The state of the art recognizes that the formation, composition and therapeutic activity of solvates and hydrates are unpredictable. The Federal Circuit has recognized a solvate as an example of a polymorph or pseudopolymorph (emphasis added):

"Polymorphs" are distinct crystalline structures containing the same molecules. These structural differences can affect various properties of the crystals, such as melting points and hardness (e.g., graphite and

diamonds are both crystalline forms of carbon)
.... [P]seudopolymorphs are often loosely
called polymorphs ... Pseudopolymorphs not only
have their molecules arranged differently but
also have a slightly different molecular
composition. A common type of pseudopolymorph
is a solvate, which is a crystal in which the
molecules defining the crystal structure "trap"
molecules of a solvent. The crystal molecules
and the solvent molecules then bond to form an
altered crystalline structure.

SmithKline Beecham Corp. v. Apotex Corp., 74 USPQ2d

1398, 1409 (Fed.Cir. 2005). The same rationale obtains
for hydrates; solvates in which the solvent is water.

Souillac, et al., Characterization of Delivery Systems,
Differential Scanning Calorimetry, pages 217-218 (in
Encyclopedia of Controlled Drug Delivery, 1999, John
Wiley & Sons, pages 212-227), recognize that different
polymorphs of the same drug can have different
therapeutic activity (emphasis added):

Because different polymorphic forms of the same
drug exhibit significant differences in their
physical characteristics, therapeutic activity
from one form to another may be different.
Studying the polymorphism of a drug and the
relative stability of the different polymorphs
is a critical part of pre-formulation
development.

Further, Vippagunta et al. (Advanced Drug Delivery Reviews, 48 (2001), pages 3-26) state "Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated in to the crystal lattice of a compound is complex and difficult." See page 18, section 3.4.

f) The artisan using Applicant's disclosure to prepare the claimed solvates and hydrates would be, e.g., an experienced process chemist with at least a BS chemistry degree.

g) Chemical reactions are known as unpredictable. In re Marzocchi, et al., 169 USPQ 367, 370 (CCPA 1971); In re Fisher, 166 USPQ 18, 24 (CCPA 1970). See above regarding the unpredictability of solvate and hydrate formation.

h) The breadth of the claims includes thousands of compounds of the instant formula (1) as well as presently unknown compounds embraced by the terms solvates and hydrates. See MPEP 2164.01(a), discussed

supra, justifying the conclusion of lack of enablement commensurate with the claims. Undue experimentation will be required to practice Applicant's claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "A compound of the formula 1" should be changed to "A compound of formula 1".

In claim 1, under the definitions of R33 and R4, there is a valence problem when R33 or R4 represent sulfonyl. See claims 2 and 3 for same.

In claim 1, under the definition of R34, the phrase "R34is hydrogen" should be changed to "R34 is hydrogen".

In claim 1, under the definition of R35, the phrase "R35is hydrogen" should be changed to "R35 is hydrogen".

In claim 3, the phrase "characterized by the formula 1a" should be changed to "of formula 1a".

In claim 5, the phrase "characterized by the formula 1a-1" should be changed to "of formula 1a-1".

In claim 8, the phrase "A compound of the formula 1a-1" should be changed to "A compound of formula 1a-1".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto et al. {JP 62/024244}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims benzimidazole compounds. Sakamoto et al. (see entire document; the provided abstract of the JP document - CA 107:124477, 1987; and especially Compounds 2 and 5 on page 3 and Compound 30 on page 5) teach benzimidazole compounds that are structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., photosensitive materials).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful photosensitive materials. The instant claimed

invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/

Laura L. Stockton

Primary Examiner, Art Unit 1626

Work Group 1620

Technology Center 1600

March 18, 2009